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Dockets Management Branch (HFA-305)
U.S Department of Health and Human Services
Food and Drug Administration

Re: Sexual Dysfunction Guidelines for Industry.

As a clinician and researcher in this field for many years I am writing to express my grave concerns regarding these guidelines. They are narrowly focussed and clinically inappropriate.

Fundamentally, the disorders listed together are SYMPTOMS not diagnoses and have very different etiologies.

More importantly low libido, or loss of sexual desire, the most common of these disorders, should not be classified as a dysfunction. Women who have low libido are not incapacitated / incapable of have sex, they just don't want to. They do not suffer dysfunction, but disinclination, and diagnostically and therapeutically this is a mood disorder. When due to low testosterone this symptom is strongly associated with loss of motivation and mild depression, but not sexual dysfunction.

The primary endpoint for evaluation of therapy is the frequency of sexual activity culminating in orgasm. This is a goal orientated male perspective and entirely flawed when evaluating female libido. In heterosexual relationships, frequency is most commonly determined by the male irrespective of the female interest, and in long standing relationships frequency is commonly an established pattern that dose not vary with intervention. Failure for frequency to change with therapy does not mean failure of response. Improvements with therapy are : interest, motivation, initiation, responsiveness, pleasure, satisfaction and the most substantial reason for intervention, QUALITY OF LIFE. These extremely important responses to treatment will be missed if not adequately evaluated.

These parameters are hardly mentioned and QOL is dismissed as trivial at the end of the document. The document also does not acknowledge that not all sexual activity has to result in orgasm to be meaningful. Pleasure from physical intimacy should not be ignored.

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No where in the document is it stated that this is a QOL issue (no one ever died of sexual disinterest/ dysfunction). There is no acknowledgement of the enormous negative impact these problems have on a woman's emotional and psychological well being. The main reason for treating woman with the primary symptoms listed is to improve their QOL, not to increase the frequency of sex in the community (as this document implies). Measuring QOL and quality of relationship as a main outcome is pragmatic, meaningful and ultimately the bottom line for intervention. The authors of this document clearly have missed this point.

Suggesting that women with depression or anxiety should be excluded from research in this field demonstrates lack of clinical experience. Women with loss of libido due to androgen depletion are commonly depressed, as are men, with intervention restoring mod and well being (refs 1-10). To exclude such individuals is excluding those most in need of intervention and those most likely to respond.

These guidelines need to be completely re-focussed. AS this document stands it will misdirect research and drug development in this field as a consequence is a disservice to womem.

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